UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ROSLYN HARRIS and MARY ALLEN, on behalf of themselves and all others similarly situated, Plaintiffs, v. PFIZER INC., Defendant.	Civil Action No. 1:21-cv-06789-DLC

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT PFIZER INC.'S MOTION TO DISMISS THE AMENDED COMPLAINT

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INTRODUCTION

Cigarette smoking is the single most preventable cause of death in the United States. It causes more than 480,000 deaths in the U.S. each year—one in five deaths. Cigarette smoking causes an even greater proportion of cancer deaths each year—one in three. For that reason, medical organizations and government agencies universally agree that the most important thing a smoker can do to reduce the risk of cancer and death is to quit smoking. Yet, millions of smokers struggle to quit because smoking is highly addictive.

Chantix (varenicline) is a highly effective prescription medicine that helps patients quit smoking. When the U.S. Food and Drug Administration ("FDA") approved Chantix for use in 2006, it proclaimed that Chantix was a "significant potential benefit to public health." *See* Gulliver Declaration, dated December 1, 2021 ("Gulliver Decl."), Ex. 1.[1] Two years later, the United States Public Health Service ("PHS") concluded that Chantix was the ***single most effective*** smoking cessation therapy on the market. By helping patients successfully quit smoking, Chantix has also significantly reduced their risk of cancer and other serious health conditions. The medicine also has a strong safety record, supported by an extensive clinical program and more than 15 years of real-world use globally. During that time, no medical, scientific, or regulatory body has suggested that Chantix could cause or increase the risk of cancer.

In 2018, FDA began investigating the potential presence of nitrosamines in medicines. Nitrosamines are organic compounds common in water and foods, including cured and grilled

[1] All exhibits referenced herein refer to the exhibits attached to the Gulliver Decl. Citations are included in the Background section. Regarding the exhibits, the Court may consider information from government agencies, including FDA and Centers for Disease Prevention and Control ("CDC"), in evaluating Plaintiffs' Amended Complaint as matters of public record. *See, e.g.*, *In re Zyprexa Prods. Liab. Litig.*, 549 F. Supp. 2d 496, 501 (E.D.N.Y. 2008) (judicial notice can be taken of "[p]ublic documents issued by … the Food and Drug Administration"); *McDonnell v. First Unum Life Ins. Co.*, 2013 WL 3975941, at *16 n.33 (S.D.N.Y. Aug. 5, 2013) (taking judicial notice of CDC website); *Geller v. de Blasio*, 2020 WL 2520711, at *2 n.1 (S.D.N.Y. May 18, 2020) (taking judicial notice of public health statistics) (J. Cote).

meats, dairy products, and vegetables. Because nitrosamines are ubiquitous in the environment, nearly every human is exposed to some level of nitrosamines in their daily lives. Certain nitrosamines—several of which are present in cigarettes—are probable or possible human carcinogens (i.e., substances that could cause cancer).

In evaluating nitrosamine levels in medicines, FDA and other regulators have established acceptable intake limits ("ADI"), which extrapolate the amount a person could ingest every single day for her entire life without increasing her theoretical cancer risk associated with the exposure above 1 in 100,000. The ADI assume that a person will take the medicine ***every day for 70 years***. Because patients are typically prescribed Chantix for twelve to twenty-four weeks only, the 70-year daily intake assumption used to set FDA's ADI limits does not reflect how Chantix is actually prescribed and used: for weeks, not decades.

Nonetheless, in July and August 2021, after testing of Chantix identified the presence of a newly-discovered nitrosamine called N-nitroso-varenicline, Pfizer voluntarily recalled consumer lots of the product and offered patients reimbursement for the cost of any unused Chantix. In September 2021, Pfizer further expanded the voluntary recall to include all Chantix lots. FDA press releases at the time informed patients that "there is no immediate risk to patients taking this medication. ***The health benefits of stopping smoking outweigh the theoretical potential cancer risk*** from the nitrosamine." Ex. 2. Moreover, as FDA acknowledged, "[t]here are ***no data available to directly evaluate the carcinogenic potential of N-nitroso-varenicline***." Ex. 3. Thus, the decision to voluntarily recall Chantix was a precautionary measure, not based on evidence of any actual cancer risk associated with real-world use of the medication.

In the wake of this precautionary, voluntary recall, Plaintiff Roslyn Harris filed this putative class action, alleging that she is concerned about getting cancer from Chantix, which she

allegedly was prescribed to help her quit smoking. On November 10, 2011 she filed an Amended Complaint ("AC"), which added a second plaintiff, Mary Allen (together with Harris, "Plaintiffs"). Plaintiffs allege that the Chantix they purchased was "economically worthless" and "unfit for human consumption" because it contained a nitrosamine. *E.g.*, AC ¶¶ 22, 24-33, 90, 95, 131. But, the AC continues to suffer from numerous pleading deficiencies requiring dismissal, including:

- Plaintiffs do not have a cognizable injury and thus lack Article III standing (Section I);
- Plaintiffs cannot privately enforce alleged violations of the Food and Drug Cosmetic Act ("FDCA") because no private right of action exists (Section II);
- Harris' claims other than express warranty are subsumed by the New Jersey Products Liability Act ("NJPLA") (Section III);
- Allen's tort claims are barred by New York's learned intermediary doctrine (Section IV);
- Plaintiffs' fraud-based claims fail for multiple reasons, including that (1) Plaintiffs do not plead a misrepresentation or omission, (2) Plaintiffs do not plead fraudulent intent, (3) Plaintiffs' fraud and negligent misrepresentation claims are barred by the economic loss doctrine, and (4) Plaintiffs fail to allege the existence of a special or privity-like relationship imposing a duty on the Pfizer sufficient to maintain a negligent misrepresentation claim (Section V);
- Allen does not state a New York General Business Law §§ 349, 350 ("NYGBL") claim because she has not pled consumer-orientated conduct or deceptive conduct (Section VI);
- Plaintiffs do not plausibly allege breach of warranty claims because (1) they do not allege any express warranty made by Pfizer, (2) they cannot plausibly allege that Chantix is unfit for its intended purpose of smoking cessation, and (3) Allen is not in privity with Pfizer, as required to state a warranty claim under New York law (Section VII); and
- Plaintiffs cannot state an unjust enrichment claim where the claim is duplicative of other claims and they do not allege a benefit that they conferred on Pfizer (Section VIII).

Therefore, the Court should dismiss the AC in its entirety and with prejudice.

BACKGROUND[2]

A. Cigarette Smoking Causes Cancer.

Tobacco use, particularly cigarette smoking, is the single most preventable cause of death in the United States. Ex. 1. Each year, cigarette smoking causes more than 480,000 deaths in the United States—about one in every five deaths. Ex. 4. Many of the health risks of smoking arise because tobacco smoke contains at least 70 chemicals—including tobacco-specific nitrosamines—that cause cancer. Ex. 5. Overall, one in three cancer deaths is caused by smoking (Ex. 6), and, on average, smokers die 10 years earlier than nonsmokers. Ex. 7. Quitting smoking ***significantly decreases*** an individual's risk of cancer. According to the CDC:

> Quitting smoking lowers the risks for cancers of the lung, mouth, throat, esophagus, and larynx. ... Within 5 years of quitting, your chance of getting cancer of the mouth, throat, esophagus, and bladder is cut in half. Ten years after you quit smoking, your risk of dying from lung cancer drops by half. If nobody smoked, one of every three cancer deaths in the United States would not happen. (Ex. 8).

B. Quitting Smoking is Difficult.

While nearly 7 in 10 adult cigarette smokers want to stop smoking, less than 8% are successful. Ex. 7. It is a "very difficult" habit to break because nicotine, the active ingredient in cigarette smoke, is highly addictive. Ex. 1 at 1. Approximately 34 million American adults and more than a billion people worldwide are addicted to nicotine. Exs. 7-10. The high relapse rate of smokers seeking to quit also is attributable to a failure to use proven smoking cessation interventions, such as Chantix. Ex. 10 at 24.

C. Chantix is Safe and Effective.

On May 11, 2006, after finding that Chantix had "significant potential benefit to public

[2] Pfizer assumes the well-pled allegations in the AC are true only for purposes of this motion, unless they are contradicted by other allegations, documents referenced in the AC, or judicially noticeable facts.

health," FDA approved the medication as the first new smoking cessation treatment to enter the U.S. market in more than a decade. Ex. 1 at 1. Chantix is intended for short-term use only. As prescribed and stated on the label, Chantix is designed to be taken for 12 or 24 weeks total. Exs. 11, 12. In 2020, the CDC explained that "[V]arenicline [Chantix] … [is] ***much safer*** than smoking. … If you keep smoking, you will keep getting exposed to the hundreds of harmful chemicals in cigarette smoke. Quit-smoking pills are used for a short time compared to continuing to smoke." Ex. 13 (emphasis added). Just two years after its introduction, the PHS concluded that Chantix was the single most effective smoking cessation therapy on the market. Ex. 14 at 109, 121.

Chantix has a "long track record" of demonstrated efficacy and "safe[ty]." Ex. 13. Chantix has been studied extensively in more than 200,000 smokers in the past fifteen years. Ex. 15.

D. FDA's Investigation of Nitrosamines in Medicines.

Nitrosamines are ubiquitous in the environment; they are common in water and foods, including cured and grilled meats, dairy products, and vegetables. Ex. 16. "Everyone is exposed to some level of nitrosamines." *Id.* Certain nitrosamines are classified as probable or possible human carcinogens by the International Agency for Research on Cancer based on laboratory testing, such as rodent carcinogenicity studies. Ex. 17 at App'x B; *see also* Ex. 2.

While nitrosamines are ubiquitous in the environment, FDA did not anticipate that nitrosamines would be present in drug products. Ex. 17 at 1. FDA is still "working to determine the source of these impurities." Ex. 3. By February 2021, it had identified seven potential nitrosamines that theoretically could be present in drug products. Ex. 17 at 4.

In response to the unexpected discovery of the potential presence of nitrosamines in other companies' medicines, in September 2020, FDA published a non-binding Nitrosamine Guidance document ("Nitrosamine Guidance") for industry, which it updated in February 2021. Ex. 16. The

Nitrosamine Guidance does not establish legally enforceable responsibilities; instead, it reflects FDA's "current thinking" and "should be viewed only as recommendations." *Id.* at 2. The Nitrosamine Guidance recommends that pharmaceutical manufacturers take steps to detect and prevent unacceptable levels of nitrosamines. *Id.* at 1.

E. ADI for Certain Nitrosamines, Including N-Nitroso-Varenicline.

FDA has published ADI for certain nitrosamines. *Id.* at 10. The ADI represents the daily intake level, which, if consumed every day for a period of ***70 years***, could create a theoretical lifetime cancer risk of 1 in 100,000. *Id.* at App'x B. A series of assumptions inform FDA's ADI calculation and are common across all nitrosamines. *Id.* FDA uses the most conservative carcinogenicity data available for the specific nitrosamine at issue, assumes that the exposed person weighs approximately 110 pounds and will take the medicine daily for 70 years. *Id.* Because of these assumptions, FDA acknowledges that, "[a] drug product intended for only short-term use … poses ***less risk*** than a drug product intended for chronic use." *Id.* at n.30.

The portion of the ADI calculation that varies across nitrosamines is the amount, in grams, of specific nitrosamine that results in a 50% tumor incidence rate in the laboratory animal most sensitive to that nitrosamine (*e.g.*, rats): a value called the "TD_{50}." *Id.* at App'x B. Because N-nitroso-varenicline was not previously known, there was "no data available to directly evaluate [its] carcinogenic potential" and establish a TD_{50}, and, thus, the ADI is not based on N-nitroso-varenicline data. Ex. 3; *see also* Ex. 17 at App'x B. The Nitrosamine Guidance explains that "information available on closely related nitrosamine compounds was used to calculate lifetime exposure limits for N-nitroso-varenicline." Ex. 3. In other words, data based on ***another*** nitrosamine was used to calculate N-nitroso-varenicline's ADI—under the assumption that the comparison nitrosamine will have a similar carcinogenicity profile. Ex. 17 at App'x B.

Based on these assumptions, the calculated ADI for N-nitroso-varenicline is 37 ng / day. Ex. 18; *see also* Ex. 17, at App'x B. Thus, a 110-pound female who were to consume 37 ng of N-nitroso-varenicline ***every day for 70 years*** would have a theoretical (albeit unproven) 1 in 100,000 chance of developing cancer. In contrast, smoking causes one in three cancer deaths. Ex. 6 at 1.

F. The Discovery of N-Nitroso-Varenicline in Chantix.

From July to September 2021, Pfizer voluntarily recalled Chantix 0.5 mg and 1 mg tablets as a precautionary measure because they may contain levels of N-nitroso-varenicline above FDA's ADI. Ex. 2; AC ¶¶ 5-11. Despite the voluntary recall, FDA informed patients that "***there is no immediate risk to patients taking [Chantix]***" since while "N-nitroso-varenicline ***may be*** associated with a potential increased cancer risk in humans," . . . [t]here are ***no data available to directly evaluate the carcinogenic potential of N-nitroso-varenicline***." Ex. 3 (emphasis added). Any theoretical "increased cancer risk [is] associated with long-term use," and Chantix is intended for short-term use only.

As such, FDA still advises patients "taking recalled [Chantix] … continue taking their [Chantix] until their pharmacist provides a replacement or their doctor prescribes a different medication that treats the same condition." Ex. 3. And, due to the obviously overwhelming cancer risk from smoking, FDA explained that "***[t]he health benefits of stopping smoking outweigh the cancer risk from the nitrosamine***." *Id.* (emphasis added).

G. Plaintiffs' Allegations.

Plaintiffs assert claims under New Jersey (Harris) and New York (Allen) law stemming from their alleged purchase of Chantix that was voluntarily recalled by Pfizer. AC ¶¶ 24-33. Plaintiffs allege that the Chantix they purchased "was unsafe" because it purportedly "contain[ed] dangerously high levels of N-nitroso-varenicline." *Id.* ¶¶ 1, 55, 91. Plaintiffs admit that they

purchased Chantix from third parties and allegedly paid a copayment to their insurers. *Id.* ¶¶ 24-33. Plaintiffs do not allege any of the following:

- the amount of certain of the copays they paid for Chantix;
- how long they smoked;
- when they sought treatment for their smoking addiction;
- when they were prescribed Chantix;
- the names of the doctors who prescribed them Chantix; or
- what they did with the Chantix that was recalled.

Plaintiffs still allege no physical injury caused by Chantix. Instead, they claim that Chantix was "worthless" and seek the return of their purchase price, along with statutory and punitive damages. *Id.* at 47-48 (Prayer for Relief).

LEGAL STANDARD

Pfizer brings this motion pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). "A case is properly dismissed for lack of subject-matter jurisdiction … when the district court lacks the statutory or constitutional power to adjudicate it." *Makarova v. U.S.*, 201 F.3d 110, 113 (2d Cir. 2000). Courts lack jurisdiction when the plaintiff does not have Article III standing. *In re Bibox Grp. Holdings Ltd. Sec. Litig.*, 2021 WL 1518328, at *5 (S.D.N.Y. Apr. 16, 2021) (Cote, J.). The plaintiff bears the burden of establishing standing. *Makarova*, 201 F.3d at 113.

Under Rule 12(b)(6), a complaint must be dismissed if it does not "contain sufficient factual matter … to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Although the Court must still accept factual allegations as true, it should not credit 'mere conclusory statements.'" *Stephenson v. Citco Grp. Ltd.*, 700 F. Supp. 2d 599, 618-19 (S.D.N.Y. 2010) (quoting *Iqbal*, 556 U.S. at 678)).

ARGUMENT

This lawsuit is a classic "no harm" consumer products liability case based solely on Pfizer's precautionary decision to issue a voluntary recall of Chantix. Plaintiffs claim that they suffered an economic harm because the Chantix was "unfit" and seek the return of their purchase price and statutory damages. *See* AC ¶ 42. Plaintiffs do not allege a physical injury caused by Chantix or a failure of Chantix to work as intended.

I. PLAINTIFFS HAVE NOT PLED AN INJURY AND THUS LACK STANDING.

A. Plaintiffs Cannot State a Claim Without an Injury.

Plaintiffs must plausibly plead an injury to state their claims other than unjust enrichment. A New Jersey Consumer Fraud Act claim requires the plaintiff to assert an "ascertainable loss." *Hoffman v. Nordic Nats., Inc.*, 2014 WL 1515602, at *5 (D.N.J. Apr. 17, 2014). To demonstrate an ascertainable loss, a plaintiff must establish "actual loss" that is "quantifiable or otherwise measurable," or "real and demonstrable," as opposed to "hypothetical or illusory" or "speculative." *Thiedemann v. Mercedes-Benz USA, LLC*, 872 A.2d 783, 792, 794-796 (N.J. Sup. Ct. 2005). The negligent misrepresentation, fraud, NYGBL, and warranty claims similarly require "damages." *Hoffman*, 2014 WL 1515602, at *5, 7 (dismissing NJCFA, fraud and warranty claims for lack of injury); *Kennedy v. Covidien, LP*, 2019 WL 1429979, at *7 (S.D.N.Y. Mar. 29, 2019) (dismissing warranty, NYGBL, and misrepresentation claims).[3]

Plaintiffs' claims suffer from a fundamental defect—plaintiffs were not injured. A plaintiff

[3] As an initial matter, Plaintiffs fail to adequately plead the facts of certain of their purchases. For example, in *Colella v. Atkins Nutritionals, Inc.*, the court held that the plaintiff's claim for a violation of the NYGBL failed in part because Plaintiff "fail[ed] to allege with specificity … what he paid for the products." 348 F. Supp. 3d 120, 142 (E.D.N.Y. 2018). So too here. Harris alleges only that she "paid a co-pay" for one of her purchases. AC ¶ 24. Allen similarly failed to indicate the amount she paid for two of her recalled Chantix purchases. *Id.* ¶ 31-32. Thus, even if all of the other elements were adequately alleged here (and they are not), these particular purchases are insufficiently alleged to establish an injury.

suffers no economic injury where they "paid for an effective [product], and … received just that—the benefit of [their] bargain." *Rivera v. Wyeth-Ayerst Labs*, 283 F.3d 315, 320 (5th Cir. 2002). "Without alleging that a product failed to perform as advertised, a plaintiff has received the benefit of his bargain and has no basis to recover purchase costs. ... Those patients who purchased [the medication] ... and who obtained effective pain relief … received the 'benefit of their bargain.'" *Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171, 176 (D.D.C. 2003) (dismissing claims).

The face of the AC demonstrates that Plaintiffs were not injured. A product is not "worthless" if it served its intended purpose, and Plaintiffs do not and cannot claim that Chantix failed to serve its intended purpose. FDA urges consumers to continue taking Chantix until a replacement therapy can be prescribed because "***there is no immediate risk to patients taking [Chantix]***" and [t]here are ***no data available to directly evaluate the carcinogenic potential of N-nitroso-varenicline***." Exs. 2, 3. Since Plaintiffs consumed their Chantix, they obtained the intended benefit of the medicine for smoking cessation. AC ¶¶ 24-27, 31-33. Moreover, if Plaintiffs consumed Chantix and quit smoking, they greatly lowered their overall health risks. *See* Ex. 2 (FDA advised patients that "[t]he health benefits of stopping smoking outweigh the cancer risk from the nitrosamine impurity in varenicline"). Thus, Plaintiffs have not been injured.

Additionally, Plaintiffs cannot plead a price premium because, by their own admissions, they paid only "co-pays" for Chantix. AC ¶¶ 24-33. They do not allege that they paid a higher co-pay for Chantix due to the undisclosed "presence of N-nitroso-varenicline." *Id.* ¶ 14. Without this allegation, Plaintiffs cannot demonstrate that they suffered a price premium injury.

B. Plaintiffs Lack Article III Standing.

Because Plaintiffs have not been injured, the Court should dismiss the AC for lack of Article III standing. At an "irreducible constitutional minimum," Article III requires Plaintiffs to

show they have ***personally suffered*** some actual or threatened injury due to defendant's conduct and that the injury is "fairly traceable" to the challenged action" and is "likely … [to be] redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992); *see also In re Bibox Grp.*, 2021 WL 1518328, at *5. They have not done so here. For example, in *Rivera*, a pharmaceutical manufacturer voluntarily withdrew Durcat from the market after receiving reports of liver failure among long-term users. 283 F.3d at 317. Plaintiffs sought to represent all patients "who … had purchased … Duract but suffered *no* physical or emotional injury" and did not claim that "Duract was ineffective as a pain killer or ha[d] any future health consequences." *Id.* (emphasis in original). "Instead, they assert[ed] that their loss of cash [wa]s an 'economic injury.'" *Id.* at 319. The Fifth Circuit dismissed the case for lack of standing because "[m]erely asking for money does not establish an injury in fact." *Id.* The court explained:

> [T]he plaintiffs' attempt to recast their product liability claim in the language of contract law. The wrongs they allege-failure to warn and sale of a defective product-are products liability claims … Yet, the damages they assert-benefit of the bargain, out of pocket expenditures-are contract law damages. The plaintiffs apparently believe that if they keep oscillating between tort and contract law claims, they can obscure the fact that they have asserted no concrete injury. Such artful pleading, however, is not enough to create an injury in fact.

Id. at 320-21.

Similarly, in *James v. Johnson & Johnson Consumer Companies*, purchasers of baby shampoo filed a consumer class action against the product's manufacturer, alleging that the manufacturer included a toxic ingredient in the shampoo. 2011 WL 198026, at *2 (D.N.J. Jan. 20, 2011). The plaintiffs did not allege that their children suffered any physical harm from the shampoo; rather, they argued that they had standing because they would not have purchased the shampoo had they known of its alleged toxicity. *Id.* The court disagreed, holding that "[o]nce the

product had been consumed ... there was no economic injury for Plaintiffs to complain of, and the fear of future injury is legally insufficient to confer standing. Plaintiffs received the benefit of their bargain so long as there were no adverse health consequences, and the product worked as intended." *Id.* Like the plaintiffs in *Rivera* and *James*, Plaintiffs received the benefit of their bargain, have no valid claim of injury, and lack Article III standing.

C. Plaintiffs Lack Standing to Seek Injunctive Relief.

Plaintiffs' request for injunctive relief also fails because they have not alleged a risk of future harm. "Past injuries . . . do not confer standing to seek injunctive relief unless the plaintiff can demonstrate that she is likely to be harmed again in the future in a similar way." *Kommer v. Bayer Consumer Health*, 710 F. App'x 43, 44 (2d Cir. 2018) (*quoting Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 239 (2d Cir. 2016)). Plaintiffs have not done so here. They assert only that Pfizer "has acted or refused to act on grounds generally applicable to the Class … as a whole." AC ¶ 59. But "[t]here is no exception … when the plaintiff is pursuing a class action." *Buonasera v. Honest Co.*, 208 F. Supp. 3d 555, 564 (S.D.N.Y. 2016).

Regardless, Plaintiffs cannot demonstrate standing for injunctive relief because they are already aware of the purported increased "risk" of cancer and thus cannot be misled in the future. *See, e.g.*, *Marino v. Coach, Inc.*, 264 F. Supp. 3d 558, 565 (S.D.N.Y. 2017) (once plaintiffs know the true price of a product, "they cannot be misled"). And, Pfizer voluntarily recalled all lots of Chantix, so there is nothing to enjoin. *Nicosia*, 834 F.3d at 239 (dismissing injunctive relief because Amazon stopped sales). Thus, Plaintiffs' request for injunctive relief must be dismissed.

II. PLAINTIFFS CANNOT ENFORCE THE FDCA.

Plaintiffs argue repeatedly that Chantix is "adulterated" and "misbranded" and thus, "illegal" to sell under the FDCA. (*See, e.g.*, AC ¶ 45). As Plaintiffs admit (*id.*), however, they

cannot "privately enforce alleged violations of the FDCA" because "no such private right of action exists." *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) (affirming dismissal). Plaintiffs' characterization of their claims does not avoid preemption.

In addition, because "[t]he FDCA lacks a private right of action … [Allen] cannot rely on it for purposes of asserting a state-law consumer claim under" the NYGBL. *Verzani v. Costco Wholesale Corp.*, 2010 WL 3911499, at *3 (S.D.N.Y. Sept. 28, 2010), *aff'd*, 432 F. App'x 29 (2d Cir. 2011) (amendment futile); *see also Conboy v. AT&T Corp.*, 241 F.3d 242, 258 (2d Cir. 2001) (a plaintiff cannot "thwart legislative intent by couching" a statutory violation without a private right of action as a NYGBL claim). Accordingly, Allen's NYGBL claim, premised on a purported violation of the FDCA, must be dismissed.

III. THE NJPLA SUBSUMES ALL BUT ONE OF HARRIS' CLAIMS.

Even if Harris had pled a cognizable injury and had standing, the NJPLA subsumes her claims except for express warranty. Under New Jersey law, the NJPLA is "the sole method to prosecute a product liability action." *Tirrell v. Navistar Int'l, Inc.*, 248 N.J. Super. 390, 398–99 (App. Div. 1991), cert. denied, 126 N.J. 390 (1991). The NJPLA was enacted "to limit the liability of manufacturers so as to balance[] the interests of the public and the individual." *Zaza v. Marquess & Nell, Inc.*, 144 N.J. 34, 47 (1996) (quotations and citations omitted). A product liability action is "any claim or action brought by a claimant for harm caused by a product, ***irrespective of the theory underlying the claim***, except actions for harm caused by breach of an express warranty." N.J. Stat. Ann. § 2A:58C–1(b)(3) (emphasis added). Thus, a plaintiff only has a compensable loss for a harm caused by a product if she can allege "personal injury" or "physical damage to property ***other than the product itself***." N.J.S.A. 2A:58C-1(b)(2) (emphasis added).

Harris has not done so here. Instead, she seeks to "shoehorn" her "failure to warn" "allegations into other causes of action" when "it is clear … that h[er] claims sound in products liability causes of action." *Barrett v. Tri-Coast Pharm., Inc.*, 518 F. Supp. 3d 810, 824 (D.N.J. 2021). This attempt fails. As the New Jersey Supreme Court has explained:

> The central focus of plaintiffs' complaints is that defendants were aware of dangers associated with lead—and by extension, with the dangers of including it in paint intended to be used in homes and businesses—and failed to warn of those dangers. ***This classic articulation of tort law duties, that is, to warn of or to make safe, is squarely within the theories included in the PLA.***

In re Lead Paint Litig., 924 A.2d 484, 503–04 (N.J. 2007) (tort claim subsumed) (emphasis added); *see also Indian Brand Farms v. Novartis Crop Prot., Inc.*, 890 F. Supp. 2d 534, 548 (D.N.J. 2012) (NJCFA and fraudulent misrepresentation claims subsumed).

For example, in *O'Donnell v. Kraft Foods, Inc.*, the plaintiffs brought a consumer class action asserting a violation of the NJCFA based on a failure to warn of the purported carcinogenic dangers of hot dogs. 2010 WL 1050139, at *3 (D.N.J. Mar. 18, 2010). The court held that:

> Plaintiffs are seeking damages … due to the increased risk of cancer they allege arises from consumption of a product. Plaintiffs' attempt to tack a [consumer fraud] remedy onto the underlying products liability claim does not alter the analysis: their theory that they are entitled to recovery of their purchase price for the hot dogs depends upon Defendants' ***alleged failure to warn of their increased risk of cancer***, a failure of "adequate warnings or instructions" covered by the [NJ]PLA.

Id. at *3 (emphasis added) (dismissing claim).

Similarly, in *Barrett*, the plaintiff brought fraud and warranty claims due to his medication's purported bacterial contamination. 518 F. Supp. 3d at 824. The court rejected the plaintiff's attempt to "shoehorn his [product liability] allegations into other causes of action" when the case was "premised on the product being defective." *Id.* The court held that the fraud-based claims were subsumed "because the alleged misrepresentation would not be actionable if … [the]

pharmaceuticals were not contaminated." *Id.*; *see also Darby v. Merck & Co.*, 949 A.2d 223, 276-277 (N.J. Super. Ct. App. Div. 2008) (claims subsumed because "the gravamen of [the] claim [i]s that [a pharmaceutical company] marketed [a medicine] fully aware of its … risk[s] [and] made misrepresentations[ ] and ... omis[sions]"); *Mendez v. Shah*, 28 F. Supp. 3d 282, 302 (D.N.J. 2014) (claims subsumed because the "essence of her claim is that the misrepresentations resulted in physical harm from the product," including "safe and effective use").

The same result follows here. The AC centers on the allegation that Pfizer failed to warn Harris that Chantix "contain[s] unsafe levels of N-nitroso-varenicline." AC ¶ 22. Thus, the NJPLA provides the sole basis for Harris' potential relief here, and her NJCFA, implied warranty, fraud, negligent misrepresentation, and unjust enrichment claims must be dismissed.

IV. THE LEARNED INTERMEDIARY DOCTRINES BARS ALLEN'S TORT CLAIMS.

Like Harris, Allen has suffered no physical injury and thus seeks to avoid dismissal by repackaging her claims as consumer fraud and economic harm claims. But this Court should still dismiss Allen's tort claims as they are all "failure to warn" claims barred by New York's learned intermediary doctrine. Per that doctrine, a manufacturer's duty is to warn the medical community, and not the patient. *Martin v. Hacker*, 83 N.Y.2d 1, 8 (1993); *Mulhall v. Hannafin*, 841 N.Y.S.2d 282, 285 (2007). "Warnings for prescription drugs are intended for the physician, whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects." *Martin*, 83 N.Y. 2d at 9. Allen's conclusion that Pfizer "engaged in extensive marketing to advertise Chantix to consumers" (AC ¶ 49) does not obviate the doctrine. *DiBartolo v. Abbott Lab'ys*, 914 F. Supp. 2d 601, 614 (S.D.N.Y. 2012) ("Contrary to plaintiff's suggestion . . . there is no trend in favor of recognizing a DTC exception.").

Here, Allen alleges that Pfizer failed to warn her that her Chantix was not really Chantix because it "contained … N-nitroso-varenicline." AC ¶¶ 31-33. But Pfizer had no duty to warn Allen at all, and Allen does not identify her prescribing physician, let alone allege that Pfizer failed to warn or made a material misrepresentation or omission to her prescribing physician about the purported risk of N-nitroso-varenicline. FDA's statements related to the Chantix recall further demonstrate that the doctrine applies: "FDA reminds patients taking recalled varenicline to continue taking their current medicine until their pharmacist provides a replacement ***or their doctor prescribes a different treatment***." Ex. 2 (emphasis added).

For example, in *Prohaska v. Sofamor, S.N.C.*, the Court dismissed a negligent misrepresentation claim because a plaintiff alleging negligent misrepresentation "must establish reliance upon a false statement or material misrepresentation or omission," and the learned intermediary rule eliminates the possibility of any such reliance. 138 F.Supp.2d 422, 447 (W.D.N.Y. 2001). "[S]ince only a doctor can prescribe and use the [medical device], any reliance on [defendant's] statements that [plaintiff] could possibly claim is eliminated by the learned intermediary rule." *Id.* Thus, Allen's tort claims are barred by the learned intermediary doctrine.

V. PLAINTIFFS' FRAUD-BASED CLAIMS FAIL FOR SEVERAL REASONS.

Plaintiffs' NJCFA, fraud and negligent misrepresentation claims also fail because they do not adequately allege a misstatement. Plaintiffs' fraud claims and the NJCFA claim (to the extent it is based on omissions) further fail because they do not allege fraudulent intent. In addition, Plaintiffs' negligent misrepresentation claim fails because Pfizer did not owe them a duty. Finally, their fraud and negligent misrepresentation claims are barred by the economic loss doctrine.

A. Plaintiffs Allege No Misstatement by Pfizer.

Plaintiffs do not allege any misstatement by Pfizer. Plaintiffs must demonstrate that Pfizer made a misstatement to prevail on their NJCFA, fraud and negligent misrepresentation claims. *See, e.g.*, *Zaman v. Felton*, 219 N.J. 199, 221-222 (N.J. 2014) (discussing NJCFA claim); *Gennari v. Weichert Co. Realtors*, 691 A.2d 350, 367 (N.J. 1997) (discussing New Jersey fraud law); *Kennedy v. Covidien, LP*, 2019 WL 1429979, at *6-7 (S.D.N.Y. Mar. 29, 2019) (discussing fraudulent and negligent misrepresentation under New York law).

Plaintiffs assert that use of the product name "Chantix" represented "that the Product would be 'Chantix' as approved by the FDA[] and would contain only varenicline as the active ingredient." AC ¶ 24. But the product name "Chantix" is accurate, since the medication's contents are the same as at the time of its FDA approval. Plaintiffs do not allege otherwise, or that FDA or any other regulatory authority has determined that Chantix was misbranded, or that the ingredients as represented in the product label were not, in fact, present in the medication. Courts routinely dismiss vague NJCFA and fraud-based claims. *See, e.g.*, *Zottola v. Eisai Inc.*, 2021 WL 4460563, at *9 (S.D.N.Y. Sept. 29, 2021) (dismissing fraud claim under New York law because "Plaintiff plead[ed] generally that Defendants did not disclose the Medications' cancer risks … But this type of vague allegation, without more, is insufficient to plead a fraud"); *Kennedy*, 2019 WL 1429979, at *7 (internal citations and quotations omitted) (dismissing negligent misrepresentation claim under New York law where the plaintiff failed to "provide any factual basis for his conclusion that Defendant's risk disclosures … were misrepresentations"); *Plastic Surgery Ctr., P.A. v. Cigna Health & Life Ins. Co.*, 2018 WL 2441768, at *7 (D.N.J. May 31, 2018) (dismissing negligent misrepresentation claim under New Jersey law where "Plaintiff has not sufficiently alleged that Defendants made an incorrect statement of past or existing fact, negligent or otherwise").

B. Plaintiffs Have Not Pled Fraudulent Intent.

Plaintiffs' fraud and NJCFA claims (to the extent they rely on a purported omission (*e.g.*, AC ¶¶ 91, 108)) also fail because Plaintiffs do not allege fraudulent intent. *See, e.g.*, *Connecticut Nat'l Bank v. Fluor Corp.*, 808 F.2d 957, 962 (2d Cir. 1987) (dismissal of fraud claim upheld where allegations undercut inference of fraudulent intent). And when "the alleged consumer fraud [for a NJCFA claim] consists of an omission, the plaintiff must sufficiently show that the defendant acted with knowledge and intent *is* an essential element of the fraud." *Cox v. Sears Roebuck & Co.*, 138 N.J. 2, 17 (1994) (emphasis in original).

Here, Plaintiffs allege no facts suggesting that Pfizer ***knew*** about the N-nitroso-varenicline in Chantix, let alone that Pfizer ***intended to withhold*** such information from Plaintiffs or hide the "true nature of the Product." AC ¶ 21. Accordingly, the AC does not satisfy Rule 12(b)(6), let alone the heightened pleading standard of Rule 9(b). Plaintiffs' conclusion of fraud is further implausible considering that Allen purchased her recalled Chantix in April 2020, and Harris purchased two of her recalled Chantix products on July 16, 2019 and August 21, 2019—long before FDA even issued guidance to the industry suggesting testing. *Id.* ¶ 31. While Plaintiffs now allege that Health Canada informed Pfizer's Canadian distributor in October 2020 that there was a "risk for formation of these ***new nitrosamines***" in Chantix (*id.* ¶ 20 (emphasis added)), a "risk" does not establish that Pfizer knew about the alleged presence of N-nitroso-varenicline in Chantix, let alone that Pfizer ***intended*** to withhold such information.

C. Pfizer Did Not Have a Special Relationship with Plaintiffs.

The Plaintiffs' negligent misrepresentation claim also fails because they were not in a special relationship with Pfizer. To prevail on a claim of negligent misrepresentation under New York law, a plaintiff must show (1) the existence of a special or privity-like relationship imposing

a duty on the defendant to impart correct information to the plaintiff; (2) that the information was incorrect; and (3) reasonable reliance on the information. *See, e.g.*, *Mahoney v. Endo Health Sols., Inc.*, 2016 WL 3951185, at **3-4 (S.D.N.Y. July 20, 2016) (Cote, J.) (internal citations omitted).

Pfizer did not owe a duty to Plaintiffs because the informed intermediary doctrine "imposes the duty to warn patients of potential side effects and health risks upon doctors, not manufacturers." *Zottola*, 2021 WL 4460563, at *10. Plaintiffs argue that Pfizer had a duty to disclose because it "possessed superior and exclusive knowledge regarding" the presence of N-nitroso-varenicline. AC ¶ 93. But superior knowledge can ***only*** form the basis of a special relationship if that party "knows that the other is acting on the basis of mistaken knowledge." *UBS AG, London Branch v. Greka Integrated, Inc.*, 2020 WL 1957530, at *7 (S.D.N.Y. Apr. 23, 2020) (internal citations and quotations omitted). *Mahoney* is instructive. 2016 WL 3951185, at *4. There, the plaintiff sued a manufacturer of fluoride tablets because the tablets allegedly contained less fluoride than stated on the product label. The Court dismissed the negligent misrepresentation claim because "[t]he plaintiff ha[d] not pled that her relationship with the defendants extended beyond that which exists between an ordinary consumer and a prescription drug manufacturer." *Id.* at *4.

So too here. Plaintiffs were not known to Pfizer. Nor do Plaintiffs plausibly allege that Pfizer knew of N-nitroso-varenicline in Chantix, *see* Section V.B, or that Pfizer intended to withhold such information from Plaintiffs such that Plaintiffs would act on the basis of mistaken knowledge. Instead, the AC admits that knowledge of N-nitroso-varenicline is new and that Pfizer recalled Chantix when it learned about N-nitroso-varenicline. Thus, Plaintiffs have not established the requisite knowledge to prompt a duty to disclose.

D. Plaintiffs' Fraud and Negligent Misrepresentation Claims are Barred by the Economic Loss Doctrine.

Under both New Jersey and New York law, a plaintiff cannot recover in tort for purely economic losses caused by a defendant's negligence. *Travelers Cas. & Sur. Co. v. Dormitory Auth.-State of New York*, 734 F. Supp. 2d 368, 378 (S.D.N.Y. 2010) (Cote, J.); *Bracco Diagnostics, Inc. v. Bergen Brunswig Drug Co.*, 226 F. Supp. 2d 557, 562 (D.N.J. 2002) (dismissing New Jersey fraud claim pursuant to the economic loss doctrine).

Plaintiffs' fraud[4] and negligent misrepresentation claims fail because they only allege economic harm. *See* AC ¶¶ 95, 112, 119-120. Thus, Allen's claims are barred under New York law by the economic loss doctrine. *See, e.g., Holborn Corp. v. Sawgrass Mut. Ins. Co.*, 304 F. Supp. 3d 392, 397 (S.D.N.Y. 2018) (dismissing tort claim based on economic loss under New York law); *Avazpour Networking Servs., Inc. v. Falconstor Software, Inc.*, 937 F. Supp. 2d 355, 364 (E.D.N.Y. 2013) (same).[5] Harris' claims are also barred by New Jersey's economic loss doctrine. The economic loss rule "preclude[s] plaintiffs from recovering under fraud and other intentional tort theories of liability where the tort claims are based on the same facts as the breach of contract claims." *Bracco Diagnostics, Inc. v. Bergen Brunswig Drug Co.*, 226 F. Supp. 2d 557, 562 (D.N.J. 2002). In particular, Plaintiffs allege fraud and negligent misrepresentation on the basis that the product they purchased failed in its intended purpose of being Chantix. AC ¶¶ 106-107, 116-119. This same allegation underpins the warranty claims. *See, e.g., Plastic Surgery Ctr., P.A. v. Cigna Health & Life Ins. Co.*, 2018 WL 2441768, at *7 (D.N.J. May 31, 2018) (dismissing

[4] While Plaintiffs allege fraud, they actually assert fraudulent concealment (AC ¶ 55(b))—the alleged concealment of N-nitroso-varenicline—which is subject to the economic loss doctrine.

[5] While "[a] limited exception to [the economic loss] doctrine exists . . . for claims of negligent misrepresentation", it does not apply here because Plaintiffs have not alleged "that there was either actual privity of contract between the parties or a relationship so close as to approach that of privity." *Travelers Cas.*, 734 F. Supp. 2d at 380; *see supra* Section V.C.

negligent misrepresentation claim pursuant to the economic loss doctrine because the claim was "comprised of the exact same allegations that form Plaintiff's breach of contract claim"); *see also Bracco*, 226 F. Supp. 2d at 562 (D.N.J. 2002) (dismissing tort claim). Thus, the economic loss doctrine bars the fraud and negligent misrepresentation claims.

VI. ALLEN'S CLAIMS FOR VIOLATION OF NYGBL MUST BE DISMISSED.

Allen has failed to state a plausible claim for violations of NYGBL. "[A] plaintiff must allege … (1) consumer-oriented conduct that is (2) materially misleading and that (3) [the] plaintiff suffered injury as a result of the allegedly deceptive act." *Orlander v. Staples, Inc.*, 802 F.3d 289, 300 (2d Cir. 2015) (citation omitted). "Deceptive acts are defined objectively[ ] as acts likely to mislead a reasonable consumer acting reasonably under the circumstances." *Boule v. Hutton*, 328 F.3d 84, 94 (2d Cir. 2003) (citation omitted). Allen's NYGBL claim fails here because she has not alleged consumer-oriented conduct or a misstatement or omission.

First, Allen has not demonstrated that Pfizer engaged in consumer-oriented conduct because Chantix must be prescribed by a doctor. New York courts routinely hold that the NYGBL does not apply in such situations. *See e.g.*, *Wholey v. Amgen, Inc.*, 165 A.D. 3d 458, 458 (N.Y. App. Div. 1st Dept. 2018). In *Wholey*, the Court dismissed claims under NYGBL in an action against a drug manufacturer "because the generally alleged deceptive practice of failing to provide adequate warnings by concealing information is, as a matter of law, not a practice directed at consumers." *Id.* Similarly, in *Amos v. Biogen Inc.*, the Court dismissed a NYGBL claim because a drug manufacturer's warning to a doctor of a drug's risks "is not a 'consumer oriented' act." 28 F. Supp. 3d 164, 1774 (W.D.N.Y. 2017); *see also Zottola*, 2021 WL 4460563, at *4.[6]

[6] The Court's decision to allow the plaintiff's NYGBL claims in *Mahoney v. Endo Health Sols., Inc.*, 2016 WL 3951185, at **3-4 (S.D.N.Y. July 20, 2016) (Cote, J.) is distinguishable because the cases cited by defendants in support of their argument involved "large private transactions between sophisticated businesses and therefore [did]

Second, the NYGBL claims also fail because Pfizer did not make a misstatement. *See supra* Section V.A (describing that the Chantix label does not contain a misstatement and that Plaintiff has not alleged any other misstatement).

Finally, Plaintiffs do not plausibly allege that Pfizer possessed material information about Chantix and failed to provide the information to Plaintiffs. Material omissions must be shown by demonstrating that "the business alone possesses material information that is relevant to the consumer and fails to provide this information." *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 85 N.Y.2d 20, 26 (1995). As with Plaintiffs' fraud-based claims, Plaintiffs allege only boilerplate allegations that Pfizer knew of N-nitroso-varenicline in Chantix. *See* Sections V.A-B. Such conclusory allegations of knowledge cannot state a claim.

VII. PLAINTIFFS FAIL TO STATE A WARRANTY CLAIM.

The warranty claims also fail for several reasons. Specifically, (1) Plaintiffs' express warranty claims fail because Pfizer did not make a false affirmation of fact, (2) Plaintiffs' implied warranty claims fail because Chantix was fit for its intended purpose, and (3) Allen's warranty claim fails because she was not in privity with Pfizer.

A. Plaintiffs Fail To Allege A Breach Of Express Warranty.

To state a claim for express warranty under either New York or New Jersey law, Plaintiffs must allege (1) that Pfizer made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain; and (3) that the product ultimately did not conform to the affirmation, promise or description. *Compare*

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not address the facts on hand." Furthermore, the Court 's decision pre-dated *Wholey*, which acknowledged that the learned intermediary doctrine applies to failure to warn claims," such as the claims at issue here. *Id.*, at n 11.

Hindermyer v. B. Braun Med. Inc., 419 F. Supp. 3d 809, 829 (D.N.J. 2019) *with Goldemberg v. Johnson & Johnson Consumer Cos.*, 8 F. Supp. 3d 467, 482 (S.D.N.Y. 2014).

Plaintiffs' express warranty claims fail because they do not allege a false "affirmation of fact or promise." *Simmons v. Stryker Corp.*, 2008 WL 4936982, at *2 (D.N.J. Nov. 17, 2008). As explained above, Pfizer did not make a false statement of fact. *See supra* Section V.A.

B. Chantix Was Fit For Its Intended Purpose.

Plaintiffs' implied warranty claims also fail because they do not allege that Chantix is unfit for its intended purpose: smoking cessation. To state an implied warranty claim under either New York or New Jersey law, Plaintiffs must allege that the product was "not 'merchantable' at the time of sale." *Hoffman*, 2014 WL 1515602, at *7 (quoting *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 600 n.8 (3d Cir. 2012); *see also Silva*, 2015 WL 5360022, at *11 ("implied contract that the goods will be of merchantable quality"). "Merchantability requires that a product conform to its ordinary and intended use." *Lieberson v. Johnson & Johnson Consumer Cos.*, 865 F. Supp. 2d 529, 542 (D.N.J. 2011). Court have determined that this means "the *general* purpose for which it should have been sold." *Id.* (emphasis in original).

The implied warranty claims fail because Plaintiffs do not allege that Chantix was unfit for its general purpose of helping nicotine addicts quit smoking. *See* AC ¶¶ 72-83. Nor could they. The AC relies upon FDA statements that demonstrate that FDA advises patients "taking recalled [Chantix] … [to] ***continue*** taking their [Chantix] until their pharmacist provides a replacement or their doctor prescribes a different medication that treats the same condition." Ex. 3 (emphasis added); *see also* AC at n. 2, 5, 6–10. In any event, FDA continues to emphasize that "[t]here are ***no data available to directly evaluate the carcinogenic potential of N-nitroso-varenicline***" (Ex. 3 (emphasis added)) and the theoretical potential cancer risks presented by N-nitroso-varenicline

"pose[] ***less risk***" because Chantix is not "intended for chronic use." Ex. 17 at n.30 (emphasis added). Therefore, the implied warranty claims fail.

C. Allen Did Not Plead Privity.

Allen's warranty claims also fail because she is not in privity with Pfizer. "[N]o implied warranty will extend from a manufacturer to a remote purchaser not in privity with the manufacturer where only economic loss and not personal injury is alleged." *Mahoney*, 2016 WL 3951185, at *5 (S.D.N.Y. July 20, 2016) (dismissing implied warranty claim); *see also Ebin v. Kangadis Food Inc.*, 2013 WL 6504547, at *6 (S.D.N.Y. Dec. 11, 2013) ("Under New York law, 'privity is normally an essential element of a cause of action for express warranty.'").[7] Here, Allen alleges she purchased Chantix from Walgreens, not Pfizer. AC ¶¶ 31-32. Thus, her warranty claims fail. *See, e.g.*, *Ebin*, 2013 WL 6504547, at *6 (dismissing claims).

VIII. THE UNJUST ENRICHMENT CLAIM FAILS.

To state a claim for unjust enrichment under either New York or New Jersey law (as applicable), the Plaintiffs must allege that (1) Pfizer was enriched by Plaintiffs, and (2) that the retention of the benefit by Pfizer is inequitable. *See Gordon v. Hain Celestial Grp., Inc.*, 2017 WL 213815, at *7 (S.D.N.Y. Jan. 18, 2017) (dismissing unjust enrichment claim); *D.R. Horton Inc. – N.J. v. Dynastar Dev., L.L.C.*, 2005 WL 1939778, at *18 (N.J. Super. Ct. L. Div., Mercer Cnty. Aug. 10, 2005) (same). As discussed above, Harris' unjust enrichment claim is subsumed by the NJPLA. The unjust enrichment claims fail for three additional reasons.

[7] *Randy Knitwear v. Am. Cyanamid Co.*, eliminated the privity requirement for express warranties arising from a defendant's public advertising or sales literature. 11 N.Y.2d 5, 11 (N.Y. 1962) ("in public advertising and on labels"). That exception is not applicable here because the representation at issue is the Chantix product name as it appears on the label. *See, e.g.*, AC ¶ 12; *see also Weisblum v. Prophase Labs, Inc.*, 88 F. Supp. 3d 283, 295-96 (S.D.N.Y. 2015). In *Mahoney*, this Court held that *Randy Knitwear* was not so limited, but that question has not yet been answered definitively by the New York Court of Appeals. Thus, Pfizer has moved to dismiss the express warranty on lack of privity in the event New York law is clarified during the pendency of this matter.

First, Harris' unjust enrichment claim should be dismissed because "New Jersey does ***not*** recognize unjust enrichment as an independent tort." *Warma Witter Kreisler, Inc. v. Samsung Elecs. Am., Inc.*, 2009 WL 4730187, at *7 (D.N.J. Dec. 3, 2009) (emphasis added) (dismissing claim). Similarly, Allen's unjust enrichment claim fails under New York law because it is duplicative. *See, e.g.*, *Yodice v. Touro College and University System*, 2021 WL 5140058, at *5 (S.D.N.Y. Nov. 4, 2021) (Cote, J.) (dismissing claim). Here, the unjust enrichment claim is premised on the same allegations as the other claims – that Chantix is "unfit." AC ¶ 103.

Second, the unjust enrichment claims fail because Plaintiffs did not confer a benefit on Pfizer. For example, in *Melendez v. ONE Brands LLC*, the Court dismissed a plaintiff's claim under New York law because "other than the conclusory assertion that [defendant] obtained 'benefits and monies,' . . . [plaintiff] neither explain[ed] how nor to what extent [defendant] benefited at [plaintiff's] expense." 2020 WL 1283793, at *8. The same result follows here. Plaintiffs allege only that they conferred a benefit on Pfizer "in the form of monies paid" for Chantix. AC ¶ 101. But they do not allege that Pfizer received any of the funds they paid retailers. *See, e.g.*, AC ¶¶ 24-29. New Jersey law requires a *direct relationship* between the parties. *See Maniscalco v. Brother Int'l Corp.*, 627 F. Supp. 2d 494, 505 (D.N.J. 2009) (emphasis added) (dismissing claim). A "benefit conferred upon a retailer not sharing in profits with the product manufacturer ***does not result*** in the manufacturer's unjust enrichment." *Alin v. Am. Honda Motor Co.*, 2010 WL 1372308, at *15 (D.N.J. Mar. 31, 2010) (dismissing claim) (emphasis added).

Finally, the unjust enrichment claims fail because Plaintiffs do not plausibly allege "why 'equity and good conscience' would require restitution" here. *Melendez*, 2020 WL 1283793, at *8. Both Plaintiffs' allegations indicate that they used the product as intended and Plaintiffs do

not allege that Chantix failed as a smoking cessation aid. *See generally* AC. In such circumstances, it would not be unjust for Pfizer to retain any benefit received.

CONCLUSION

For the reasons stated above, Pfizer respectfully requests that the Court dismiss Plaintiffs' Amended Complaint in its entirety and with prejudice.

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Respectfully submitted,

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